

PATENT COOPERATION TREATY

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NOTIFICATION OF ELECTION
(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

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|---|
| Date of mailing (day/month/year) 07 March 2001 (07.03.01) |
| International application No. PCT/GB00/02504 |
| International filing date (day/month/year) 29 June 2000 (29.06.00) |
| Applicant LAU, Kim, King, Tong et al |

Applicant's or agent's file reference
N.77228A TAC

Priority date (day/month/year)
29 June 1999 (29.06.99)

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

19 January 2001 (19.01.01)

in a notice effecting later election filed with the International Bureau on:

2. The election was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

| | |
|---|---|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35 | Authorized officer Juan Cruz Telephone No.: (41-22) 338.83.38 |
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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|--|---|--|
| Applicant's or agent's file reference N.77228A TAC | FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. | |
| International application No. PCT/GB 00/ 02504 | International filing date (day/month/year) 29/06/2000 | (Earliest) Priority Date (day/month/year) 29/06/1999 |
| Applicant | | |

DREW SCIENTIFIC LIMITED

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. **Certain claims were found unsearchable** (See Box I).

3. **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

as suggested by the applicant.

because the applicant failed to suggest a figure.

because this figure better characterizes the invention.

None of the figures.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| | | | |
|--|--|--|---|
| Applicant's or agent's file reference N.77228A TAC | FOR FURTHER ACTION | | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
| International application No. PCT/GB00/02504 | International filing date (day/month/year) 29/06/2000 | Priority date (day/month/year) 29/06/1999 | |
| International Patent Classification (IPC) or national classification and IPC C12Q1/00 | | | |
| Applicant DREW SCIENTIFIC LIMITED | | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

| | |
|---|---|
| Date of submission of the demand 19/01/2001 | Date of completion of this report 05.10.2001 |
| Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized officer Luzzatto, E Telephone No. +49 89 2399 8169 |



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/02504

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
Description, pages:

1-12 as originally filed

Claims, No.:

1-21 as originally filed

Drawings, sheets:

1-6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/02504

the drawings, sheets:

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|------|-------------------|
| Novelty (N) | Yes: | Claims 4-13,18-21 |
| | No: | Claims 1-3,14-17 |
| Inventive step (IS) | Yes: | Claims none |
| | No: | Claims 4-13,18-21 |
| Industrial applicability (IA) | Yes: | Claims 1-21 |
| | No: | Claims |

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

PART V

- 1) D1 (WO-A-9521934) discloses an amperometric biosensor suitable for the determination of hydrogen peroxide which comprises glucose oxidase and a ferricyanide mediator (see p. 2, l. 16-p. 4, l. 26, claims). The Applicant contends that the biosensor of D1 works in a different way from the claimed one, without however giving any further details. Although D1 does not disclose the reaction of the reduced form of the mediator with hydrogen peroxide, it would appear that the said mediator **would** react, in his reduced form, with H_2O_2 . Therefore, since claim 1 merely relates to a mediator **capable** of being H_2O_2 -selective in its reduced, D1 appears to anticipate the subject-matter of claims 1-3, 14-17 (Art. 33(2) PCT).
- 2) The subject-matter of claims 4-13, 18-21 is not disclosed in any of the available documents and meets thus the novelty requirements of Art. 33(2) PCT.

2.1 If the Applicant had convincingly indicated that the biosensor of D1 comprises a different mediator from that of the present application, then novelty would have been acknowledged. However, the said claims would have lacked an inventive step (Art. 33(3) PCT) in view of D1 and D2.

D2 (EP-A- 400918) discloses an amperometric sensor comprising the use of quaternary ammonium (such as cetylpyridinium) derivatives of ferricyanide as redox mediators which, in their reduced form are selective for hydrogen peroxide. The sensor is used for the determination of various analytes, such as ethanol. The sensor of D1 appears however not to be suitable for determining the concentration of hydrogen peroxide in a sample and therefore does not appear to anticipate the subject-matter of claim 1.

Starting from D1, which is considered to be the closest prior art, the skilled person would have followed the clear indication of D2 as to the advantages of the mediator it discloses and as to the plurality of enzymes which could be used therewith (see col. 3, l. 50-col. 5, l.45, ex. 19-22) and would have thus combined the biosensor of D1 with the mediators of D2; he would have therefore obtained the subject-matter of the said claims 1-3, 14-17, along with that of claims 4, 5, 8, 9 in an obvious way.

Claims 4, 5, 8 and 9 lack thus an inventive step (Art. 33(3) PCT).

2.2 The description fails to provide any evidence that the sensor to which claims 6 and 7 relates exhibits any unexpected effect and moreover the mediator of claim 6 is well known in the art (see D5, CA abstract AN 117:61987). Hence no inventive step therefor can be acknowledged. If the Applicant had held the view that such an effect is present, then an objection under A. 84 (lack of support) would have arisen with respect to cl. 7, in view of the absence in the description of any experimental evidence as to the use of such compounds in the claimed sensor.

2.3 The use of polymers to which the redox mediator is bound is known in the art of sensors (see D3, US-A-4711245, col. 6, l. 4-15). Hence, and in view of the absence of any indication of the technical problem that could be solved by the subject-matter of claims 10-11 and of the absence of any experimental data showing any surprising effect thereof, claims 10-13 lack an inventive step (Art. 33(3) PCT).

8) D4 (Electroanalysis, vol. 10(9), 591-596, Svitel et al. (corresponding to CA abstract AN: 129:257226 cited in the SR)) describes the preparation of quaternary ammonium derivatives of ferricyanide such as tetraheptyl ammonium ferricianide (RN: 213401-33-3). The compounds disclosed in D2, D4 and D5 are excluded from the scope of claim 18 by way of disclaimer: the subject-matter of the claim is thus novel. However, in view of the fact that:

- the only compound for which experimental results are shown is tetrahexyl ammonium ferricyanide and that even for this compound no evidence is provided as to any unexpected effect compared to the compounds known from the prior art, and
- that the claimed compounds are structurally very similar to those claimed, no inventive step can be acknowledged for the subject-matter of claim 18 and of claims 19-21 dependent thereon, whose features do not exhibit any unexpected effect.

PART VII

1) Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D3 is not mentioned in the description, nor are these documents identified therein.

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
4 January 2001 (04.01.2001)

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(10) International Publication Number
WO 01/00865 A3

(51) International Patent Classification⁷: C12Q 1/00

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9915181.3 29 June 1999 (29.06.1999) GB

(71) Applicant (for all designated States except US): DREW SCIENTIFIC LIMITED [GB/GB]; Sowerby Woods Industrial Estate, Park Road, Barrow-in-Furness, Cumbria LA14 4QR (GB).

(72) Inventors; and

(75) Inventors/Applicants (for US only): LAU, Kim, King, Tong [GB/GB]; Birkbeck College, Department of Chemistry, Gordon House, 29 Gordon Square, London WC1H

(74) Agents: CRESSWELL, Thomas, Anthony et al.; J.A. Kemp & Co., 14 South Square, Gray's Inn, London WC1R 5LX (GB).

(81) Designated States (national): CA, US.

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Published:
— with international search report

(88) Date of publication of the international search report:
13 September 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/00865 A3

(54) Title: AMPEROMETRIC SENSOR

(57) Abstract: An amperometric sensor suitable for determining the concentration of hydrogen peroxide in a sample, said sensor comprising a ferricyanide compound which, in reduced form, functions as a mediator specific to hydrogen peroxide.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/02504

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12Q1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data, EMBASE, MEDLINE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------|---|---|
| X | EP 0 400 918 A (NAKANO VINEGAR CO LTD) 5 December 1990 (1990-12-05) the whole document | 1,2,4,5, 14,15,17 3,7-13, 16,18-21 |
| X | DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; SHIIKI, MIKIO ET AL: "Ethanol sensor using alcohol dehydrogenase" retrieved from STN Database accession no. 117:61987 CA XP002164342 abstract & JP 04 070558 A (YAMAGUCHI-KEN, JAPAN) 5 March 1992 (1992-03-05) | 1,2,4-6, 14,15,17 |
| | | -/- |

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

30 March 2001

Date of mailing of the international search report

12/04/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Luzzatto, E

INTERNATIONAL SEARCH REPORT

Internat'l Application No
PCT/GB 00/02504

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------|--|-----------------------|
| Y | DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; SVITEL, JURAJ ET AL: "Composite biosensor for sulfite assay. Use of water-insoluble hexacyanoferrate(III) salts as electron-transfer mediators" retrieved from STN Database accession no. 129:257226 CA XP002164341 cited in the application abstract & ELECTROANALYSIS (1998), 10(9), 591-596 , | 3,7-13, 16,18-21 |
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| A | US 4 711 245 A (HILL HUGH A O ET AL) 8 December 1987 (1987-12-08) cited in the application column 6, line 4 - line 16 | 10,11 |
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern. Application No

PCT/GB 00/02504

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